REMARKS

In response to the Communication mailed on May 19, 2004, Applicant respectfully requests that the Examiner consider the following remarks. The Examiner stated that Applicant's reply did not fully point out the distinctions believed to render the newly presented claims patentable. **Accordingly, on page 12 of this response, Applicant has provided further explanation regarding the patentability of New Claims 62 and 63.** Applicant has reproduced the Office Action Response in its entirety for the Examiner's convenience.

Rejection under 35 U.S.C. § 112

The Examiner rejected Claims 12-20 and 50 under 35 U.S.C. § 112. Claims 12-20 and 50 have been withdrawn, without prejudice. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 112.

Rejection under 35 U.S.C. § 101

The Examiner rejected Claim 44 under 35 U.S.C. § 101 because, according to the Examiner, Claim 44 positively claimed a living tissue. Applicant has amended Claim 44 to recite *at least one anchor, wherein said at least one anchor is coupled to at least a portion of the anulus augmentation device.* Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 101.

Rejection under 35 U.S.C. § 102

The Examiner rejected Claims 1-8, 10-12, 14-22, 45, 47, and 55-61 under 35 U.S.C. § 102(b) as being anticipated by WO 97/26847 to Felt et al. ("Felt").

The Examiner rejected Claims 1 and 46 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,244,630 to Bao et al. ("Bao").

Claim 43 stands unrejected over the prior art. Applicant has rewritten dependent Claim 43 as an independent claim. Claim 43 now expressly incorporate the limitations of Claim 1. Accordingly, Applicant respectfully submits that Claim 43 is allowable over the prior art.

Applicant has amended Independent Claims 1 and 21 to recite a nuclear augmentation material that comprises a fluid that is incapable of changing phase in vivo. No new matter has

been added by this amendment. Support for this amendment can be found in the originally filed specification. For example, on page 50, ¶¶ 233-4, the specification provides:

> *The augmentation material 554 may remain "fluid" after the infusion step,* or may polymerize, cure, or otherwise harden to a less flowable or nonflowable state.[1]
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> Additional additives and components of the nucleus augmentation material are recited below. In general, *the nature of the material 554 may remain constant during the deployment and post-deployment stages* or may change, from a first infusion state to a second, subsequent implanted state.[2]

The specification also discloses several fluids that are inherently incapable of changing phase in the disc environment. For example, on page 50, ¶ 232, the specification provides:

> Exemplary fluid nuclear augmentation materials 554 include, but are not limited to, various pharmaceuticals (steroids, antibiotics, tissue necrosis factor alpha or its antagonists, analgesics); growth factors, genes or gene vectors in solution; biologic materials (hyaluronic acid, non-crosslinked collagen, fibrin, liquid fat or oils); synthetic polymers (polyethylene glycol, liquid silicones, synthetic oils); and saline.

One of ordinary skill in the art would understand that many, if not all, of these fluids simply cannot change phase in the disc environment. In other words, at body temperature, these fluids remain fluid.

On page 49-50, ¶ 231, the specification further provides:

> Fluid nuclear augmentation 554 is particularly well-suited for use in various aspects of the current invention because it can be delivered with minimal invasiveness and because it is able to flow into and fill minute voids of the intervertebral disc space. Fluid nuclear augmentation 554 is also uniquely suited for maintaining a pressurized environment that evenly transfers the force exerted by the endplates to the anulus augmentation device and/or the anulus. However, fluid nuclear augmentation materials 554 used alone may perform poorly in discs 15 with a degenerated anulus because the material can flow back out through anulus defects 8 and pose a risk to surrounding structures. This limitation is overcome by several embodiments of the current invention because the barrier 12 shunts the pressure caused by the fluid augmentation 554 away from the damaged anulus region 8 and toward healthier regions, thus restoring function to the disc 15 and reducing risk of the extrusion of nuclear augmentation materials 7 and fluid augmentation material 554.

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[1] Emphasis added.
[2] Emphasis added.

Although phase-changing materials are disclosed in the specification, the embodiment described above clearly contemplates a liquid fluid that is incapable of changing phase and that requires an anulus augmentation device to prevent undesired flow of a liquid into surrounding disc anatomy.

Claims 1 and 21 are novel and nonobvious over the cited references. Felt's purpose is to deliver a curable material into the disk so that it can harden and function as cartilage. Felt at page 3, lines 16-25. Felt discloses a biomaterial that must be cured (e.g., undergo a phase change) within the disc environment. Indeed, Felt narrowly defines a biomaterial as "a material that is capable of being introduced to the site of a joint by minimally invasive means, and be cured to provide desire physical-chemical properties in vivo." Felt at page 5, lines 26-29. Felt teaches that "[s]uch biomaterials are also curable, meaning that they can be cured or otherwise modified, in situ, at the tissue site, in order to undergo a phase or chemical change sufficient to retain a desired position and configuration." Felt at page 18, lines 26-28. Indeed, Felt teaches away from fluids that cannot be cured or are incapable of changing phase. In Felt, curing is critical because in the cured state, the biomaterial can achieve tensile strength and stiffness. Felt at page 19, lines 22-23. Moreover, an uncurable liquid (e.g., a liquid that remains a liquid in the disc environment) would be inoperable using Felt's device or method. Accordingly, Applicant's Claims 1 and 21, and the claims which depend from them are patentable over Felt.[3]

Bao simply discloses an expandable plug for sealing a defect in the anulus. Bao does not teach or suggest a fluid nuclear augmentation material that remains fluid in vivo. Accordingly, Claims 1 and 46 are patentable over Bao.

Accordingly, in view of the above remarks, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 1-8, 10-12, 14-22, 45-47, and 55-61 under U.S.C. § 102(b).

[3] The dependent claims are also patentable because they recite independently patentable features.

Rejection under 35 U.S.C. § 101

Applicant has added new claims 62 and 63. No new matter has been added by these claims. Support for new Claim 62 (directed to an absorbable fluid) can be found, inter alia, in the originally filed specification at page 8, ¶ 28. Support for new Claim 63 is discussed above (*see* e.g., ¶¶ 231-4 of originally-filed specification).

New Claim 62 is patenable over the cited art because Claim 62 depends from an allowable base claim, namely Claim 1, and recites one or more further independently patentable features.

New Claim 63 is patentable over the cited art because, inter alia, Claim 63 recites *"wherein said nuclear augmentation material comprises a fluid, wherein said fluid is in a liquid state during insertion into the disc and wherein said fluid remains as a liquid while in the disc environment."*

New Claim 63 is patentable over Felt because, as discussed above, Felt discloses a biomaterial that must be cured within the disc environment. Indeed, Felt narrowly defines a biomaterial as "a material that is capable of being introduced to the site of a joint by minimally invasive means, and be cured to provide desire physical-chemical properties in vivo." Felt at page 5, lines 26-29. In Felt, curing is critical because in the cured state, the biomaterial can achieve tensile strength and stiffness. Felt at page 19, lines 22-23. Moreover, a fluid that is a liquid and remains as a liquid while in the disc environment (as recited in New Claim 63) would be inoperable using Felt's device or method because Felt's device requires a biomaterial is cured to "retain a desired position and configuration." Felt at page 18, lines 26-28.

New Claim 63 is patentable over Bao because Bao only discloses an expandable plug for sealing a defect in the anulus. Nowhere does Bao teach or suggest a fluid nuclear augmentation material *that remains liquid in vivo.*

Accordingly, Applicant respectfully asserts that Claims 62 and 63 are patentable over the cited art.

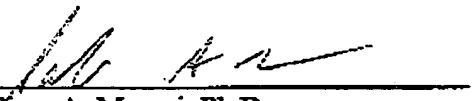
CONCLUSION

In view of the foregoing remarks, Applicant respectfully asserts that the present application is fully in condition for allowance. If any issues remain that may be addressed by a phone conversation, the Examiner is invited to contact the undersigned at the phone number indicated below.

Appropriate fees have been submitted herewith. No further fees are believed to be due. However, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 17, 2005 By: 

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